

REMARKS/ARGUMENTS

After entering these amendments, claims 1-8, 13-17 and 21-29 will be pending. Claims 9-12 and 18-20 have been canceled; whereas, claim 29 has been added.

THE REJECTIONS UNDER 35 U.S.C. § 112:

A: Claims 1-8, 12-13 and 15-28 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse.

A-1: Specifically, Claim 1 and the claims dependent thereon were rejected because the Examiner deemed the phrase “alternatively, R^2 and R^3 join to form a 5- or 6-membered ring optionally substituted with –O- or $N(R^4)$ –” to be indefinite. Applicants have canceled claims 12 and 18-20 and have amended claims 1, 13, 14 and 15 and thereby claims 2-8, 16-17 and 21-28, which are dependent thereon, to delete the phrase “alternatively, R^2 and R^3 join to form a 5- or 6-membered ring optionally substituted with –O- or $N(R^4)$ –”. In light of the above amendments, applicants request the Examiner withdraw these rejections under 35 U.S.C. § 112, second paragraph as they are now moot.

A-2: Further, Claim 1 and the claims dependent thereon were rejected because the Examiner deemed the phrase “alternatively, R^{12} and R^{13} join to form a 5- or 6-membered ring optionally substituted with –O- or $N(R^4)$ –” to be indefinite. Applicants have canceled claims 12 and 18-20 and have amended claims 1-6 and 13-14 and thereby claims 7-8, 15-17 and 21-28, which are dependent thereon, to delete the phrase “alternatively, R^{12} and R^{13} join to form a 5- or 6-membered ring optionally substituted with –O- or $N(R^4)$ –”. In light of the above amendments, applicants request the Examiner withdraw these rejections under 35 U.S.C. § 112, second paragraph as they are now moot.

B: Claims 18-20 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse.

Applicants have canceled claims 18-20. In light of the above amendments, applicants request the Examiner withdraw these rejections under 35 U.S.C. § 112, second paragraph as they are now moot.

C: Claims 22-25 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse.

C-1: Specifically, the Examiner stated that the claims were unclear as to which disorders are associated with 5HT2a- and 5HT2c-receptor modulation (claims 24-25 and 22-23, respectively). (Page 4, June 25, 2003 Office Action). Applicants direct the Examiner's attention to the specification as originally filed for a listing of disorders associated with 5HT2a- and 5HT2c-receptor modulation. 5HT2a- and 5HT2c-receptor modulation has been shown to affect disorders such as, for example, schizophrenia, anxiety, depression, migraines, psychoses, mood, behavior, hallucinogenesis, appetite, thermoregulation sleep sexual behavior, penile erections, motor activity, neuroendocrine function and hypoactivity. (Page 2, line 28 to page 3, line 13).

C-2: Further, the Examiner stated that "[s]uppose that a given modulator (agonist or antagonist) 'compound X' when administered to a patient with Disease D does not obtain a response...Thus, how many need to be tested?" (Page 4, June 25, 2003 Office Action). The Examiner's statement that compound X might not treat Disease D in one patient but might treat Disease D in a second patient is a conclusory opinion and as such not a sufficient basis for a rejection under 35 U.S.C. § 112, second paragraph. "Method claim for administration of claimed pharmaceutical compound is not rendered indefinite by its recitation of diverse utilities, since skilled worker in art could readily optimize effective dosages and administrative regimens for each of recited utilities." Ex parte Skuballa, 12 U.S.P.Q.2d 1570, 1571 (USPTO Board of Patent Appeals and Interferences 1989).

C-3: Additionally, the Examiner stated that "[i]t may be that the wrong dosage or dosage regimen was employed. It is quite common for pharmaceuticals to work at one dosage, but not at another which is significantly higher or lower. Furthermore, the dosage regimen may be varied--should the drug be given e.g. once a day, or four times in divided dosages? Thus, how many dosages and dosage regimens must be tried". (Page 4, June 25, 2003 Office Action). The phrase "therapeutically effective amount" that is found in claims 22-25 is definite to one of skill in the art because determination of such amounts is not beyond skill of the art and does not involve undue experimentation. In re Halleck, 164 U.S.P.Q. 647, 649 (CCPA 1970).

C-4: Further, the Examiner states "[i]t may be that X simply isn't potent enough for Disease D, but that another inhibitor Y is potent enough. (Page 5, June 25, 2003 Office Action). The fact that some compounds of the present invention might not effectively treat a given disease while other compounds of the present invention might effectively treat a given disease does not render the claims indefinite. In re Wands, 8 U.S.P.Q.2d 1400, 1406 (Fed. Cir. 1988) (wherein the court held applicants' claims to be definite in which some of applicants' cell lines were effective while others were ineffective at producing the desired antibodies).

C-5: Further still, the Examiner states "'if D responds to Y but not to X, can one really conclude that D falls within the claim?" (Page 5, June 25, 2003 Office Action). The fact that

some compounds of the present invention might not effectively treat a given disease while other compounds of the present invention might effectively treat a given disease does not render the claims indefinite. In re Wands, 8 U.S.P.Q.2d 1400, 1406 (Fed. Cir. 1988) (wherein the court held applicants' claims to be definite in which some of applicants' cell lines were effective while others were ineffective at producing the desired antibodies).

C-6: Additionally, the Examiner states that "suppose that X really works but only when combined with Z." Applicants do not believe this scenario renders any of claims 22-25 indefinite. Applicants direct the Examiner's attention to the fact that claims 22-25 utilize "comprising" language which on its face would cover methods of treatment utilizing the compounds of the present invention and any additional agent that one of skill in the art might later add.

C-7: Finally, the Examiner states "any disorder can be treated with any drug, although the treatment might not be successful. Assuming that 'successful treatment' is what is intended, what criterion is to be used?" Applicants direct the Examiner's attention to the fact that claims 22-25 recite "[a] method for treating a human suffering from a disorder..." It is patently clear that applicants intend a successful treatment of the claimed disorder. Based upon the wealth of literature cited in the specification, one of skill in the art will reasonably understand that successful treatment of the disorder is claimed. The Examiner's rejection of claims 22-25 based upon the possibility of an unsuccessful treatment does not have sufficient basis because "applicants' broad statement of utility is reasonable and believable" the claims are definite. Ex parte Hageman, 179 U.S.P.Q. 747, 749 (USPTO Board of Appeals).

In light of the above arguments, applicants request the Examiner withdraw these rejections under 35 U.S.C. § 112, second paragraph as they are without merit.

NEW CLAIMS:

Applicants have added new claim 29 to recite the specific compounds previously claimed in canceled claims 18-20. Specifically, new claim 29 recites only the compounds wherein variable "X" in formula (I) is " $-\text{CH}_2$ ". As all compounds presently claimed in new claim 29 were recited in the specification as originally filed and claimed in canceled claims 18-20, there is no issue of new matter.

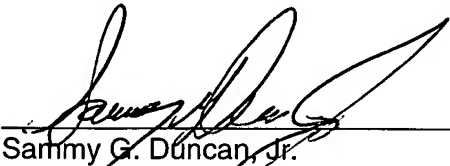
CONCLUSION:

In view of the above amendments and remarks, applicants respectfully submit that the present application is in condition for allowance. Additionally, as stated above, applicants respectfully request a two (2) month extension of time pursuant to 37 C.F.R. §1.136(a)(1) up to and including November 25, 2003 for responding to the Office Action. Please charge \$420.00 pursuant

to 37 C.F.R. §1.17(a)(2) to Deposit Account No. 19-3880 for the extension of time. No other fee is believed due for the filing of this Amendment; however, should any additional fees be due please charge said fees to Deposit Account No. 19-3880. A copy of this page is enclosed.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
(609) 252-6270



Sammy G. Duncan, Jr.
Attorney for Applicant
Reg. No. 46,675

Date: November 24, 2003